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Description

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Backing material for medical purposes

10 The invention relates to a backing material for medical purposes, preferably a medical plaster, which is coated on at least one side completely or partially with a doped adhesive composition.

15 As backing materials for medical purposes, numerous materials based on films, wovens, knits, nonwovens, gels or foams have already been disclosed and are also employed in practice. The materials, which are often coated with a self-adhesive composition as well, are required to be skin-compatible, generally permeable to air and water vapour, and also easy to model and conformable. Based on these requirements, a very thin or soft backing is frequently preferred. For handling and in use, however, the backing materials are also required to be of sufficient strength and possibly of limited extensibility. Furthermore, the backing material should retain sufficient strength and low extensibility even after becoming wet through.

20 Thin backings, especially those made of nonwovens, are highly permeable to air and water vapour. For certain applications, however, their strength is too low and their elongation too high. Moreover, the cushioning effect is inadequate for these favourable backings.

25 Specific applications, an example being rheumatism plasters, require inelastic backings having high strength in the direction of stress. This is achieved

by using woven or knitted fabric backings, usually of cotton or viscose. Backing materials of this kind, with appropriately high basis weight, are generally cost-intensive. High conformability and modelability can only be achieved by means of woven fabric of relatively low strength. When such fabrics are stressed, however, they generally exhibit too low a degree of cushioning, which is undesirable for the application.

10 When the dressings listed become wet through, they generally lose strength or become more extensible. This is likewise undesirable for their use and has to date been compensated by more frequent changing of dressings, which, however, is cost-intensive.

15 Thus, AU 73555/74 describes by way of example a glass filament-reinforced backing material for medical application based on foam.

20 US 4,668,563 describes a glass fibre-reinforced material which, however, is elastic. All backing materials mentioned, however, are not reinforced by stitching.

25 DE 44 42 092 and DE U 94 01 037 describe adhesive tapes based on stitchbonded webs which are partially coated on the reverse side of the backing. Such adhesive tapes are used preferably in cable bandaging.

DE 44 42 093 is also based on the use of a nonwoven as  
30 backing for an adhesive tape; in this case, a cross-laid fibre web is described which is reinforced by the formation of loops from the fibres of the web.

DE 44 42 507 likewise discloses an adhesive tape for cable bandaging, but bases it on so-called Kunit or  
35 Multikunit webs.

A utility or special suitability of these backing

materials for medical purposes, however, cannot be inferred from the documents cited. In particular, the publications give indications neither of sufficient skin compatibility of the adhesive compositions nor of functionally secured bonding on the skin or an advantageous permeability to air and water vapour. Furthermore, doping with active substances is not mentioned.

10 US 4,773,238 describes a fibre web with lengthwise over stitching, the stitching seams being intended to amount to no more than 20% by weight based on the weight of the total nonwoven. Proposed in accordance with the invention is the utility as an insert for  
15 filters in dust filtration.

US 4,967,740 gives a general disclosure of backing materials for use in medical supply, which are produced in a one-step process. In this process, the backing is  
20 impregnated simultaneously with an elastomer and with a release solution. In this way, the material can be presented without release paper on a roll. Doping with active substances is not mentioned.

25 In a listing of a large number of appropriate backings, mention is made, inter alia, of over stitched nonwovens, without the skilled worker being given any indication as to how the nonwoven should, specifically, be configured in order to meet the requirements placed on  
30 a medical backing.

Transdermal therapeutic systems (TTS) are forms of administration of medicaments which deliver one or more medicaments to the skin over a defined period at their  
35 site of use. A distinction is made between systemic and local administration forms.

With systemic administration forms, the active substance passes through the skin into the blood circulation by diffusion and is able to act within the body as a whole.

- 5 Local administration forms, on the other hand, act only at the applied sites. The active substance remains in the skin or in the underlying layers.

10 Strongly adhering plasters are usually coated over the whole of their area with a rubber adhesive composition. These adhesive compositions then permit secure bonding, for example at critical points such as joints, over the duration of several days. The adhesive bonding of such products to the skin, however, shows distinct skin  
15 irritations following removal, and mechanical stressing of the skin. Without auxiliary means, the bond cannot be released painlessly.

20 Further adhesive compositions are based on acrylate systems or on block copolymers.

The abovementioned adhesive compositions may be pressure-sensitive self-adhesive compositions, in which case the compositions may be present for processing in  
25 a carrier matrix. The carrier matrix is understood to comprise common organic or inorganic solvents or dispersants.

30 Systems without a carrier matrix are referred to as 100% systems and are likewise not unknown. They are processed in the elastic or thermoplastic state. A common mode of processing is that of the melt.

Pressure-sensitive hot-melt adhesive compositions of this kind have also already been described in the prior  
35 art. They are based on natural or synthetic rubbers and/or other synthetic polymers.

An advantage of the 100% systems is that they avoid the operation of removing the carrier matrix, i.e. the auxiliary means, thereby raising the productivity of processing and at the same time reducing the expenditure on machinery and the energy costs. In addition, this reduces the occurrence of residues of the carrier matrix. This, in turn, is to the benefit of a reduction in the allergenic potential.

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Because of their high level of hardness, adhesion to the skin is a problem for such 100% systems.

It is also known to apply such self-adhesive compositions not only over the entire area but also in the form of a pattern of dots, for example by screen printing (DE-C 42 37 252), in which case the dots of adhesive may also differ in their size and/or distribution (EP-B 353 972), or by gravure printing of lines which interconnect in the longitudinal and transverse directions (DE-C 43 08 649).

The advantage of the patterned application is that the adhesive materials, given an appropriate porous backing material, are permeable to air and water vapour and, in general, are readily redetachable.

A disadvantage of these products, however, is that if the area covered by the adhesive layer, which per se is impermeable, is too large there is a corresponding reduction in the permeability to air and water vapour, and the consumption of adhesive composition rises; and also, if the area covered by the adhesive layer is small, the adhesion properties deteriorate, i.e. the product is detached too readily from the substrate, especially in the case of heavy, textile backing

materials.

Numerous embodiments of active substance plasters have already been described in the prior art, some of which  
5 operate in accordance with the reservoir principle, where the active substance is delivered, for example, via a membrane, in some cases also with a matrix system or with a relatively complex multilayer structure.

10 It is also known that the adhesive composition of the plaster may be employed as the active substance matrix. In addition to self-adhesive compositions applied from solution, hot-melt adhesive compositions have also been proposed for this purpose, as for example in  
15 EP-A 663 431, EP-A 452 034, EP-A 305 757, DE-A 43 10 012, DE-A 42 22 334 and DE-C 42 24 325. The active substances listed in these documents, if named at all, have been systemic ones. Use of the backing of the invention is not described.

20 As examples of active substance plasters, mention may be made of the active substance plasters which aid the circulation, belonging to the group of the locally active therapeutic systems. The use of such plasters is  
25 indicated for the treatment of rheumatic complaints, sciatica, lumbago, stiff neck, shoulder/arm pain and also muscular strains and sprains, muscular aching or muscle, joint and nerve pain in the region of the locomotor system.

30 Capsaicin, belladonna and nonivamide are known active substances in such locally acting, circulation-aiding plasters. Because of their use on the locomotor system they are generally required to adhere strongly.  
35 Usually, the plasters are coated over their whole area with a resin-rubber adhesive composition which

comprises the active substance.

However, plasters of this kind, which usually have to be applied over a relatively large area, may in some cases lead to mechanical skin irritations following removal in the case of sensitive patients.

The disadvantage depicted also applies to active substance plasters comprising substances other than those mentioned.

For instance, WO 94/02123 describes an active substance plaster based on pressure-sensitive hot-melt adhesive compositions and comprising low-melting and/or readily volatile active substances in a concentration of from 2.5 to 25% by weight. Use of the backing of the invention is not described.

EP 0 663 431 A2, EP 0 443 759 A3, EP 0 452 034 A2 and US 5,371,128 describe uses of pressure-sensitive, silicone-based hot-melt adhesives with various additives and in differentiated structural forms. Use of the backing of the invention is not described.

DE 43 10 012 A1 describes the structure of a dermal therapeutic system comprising meltable poly(meth)acrylate mixtures.

In particular, the release of a plurality of active substances from polymer systems which [lacuna] only one polymer type appears difficult. Systems comprising two or more polymer types are, however, critical in their compatibility. Use of the backing of the invention is not described.

DE 43 16 751 C1 describes a multi-chamber system for administering active substances.

EP 0 439 180 describes an active substance plaster for administering tulobuterol.

EP 0 305 757 describes an active substance plaster for administering nicotine.

5 EP 0 305 758 describes an active substance plaster for administering nitroglycerine.

EP 0 305 756 describes an adhesive composition of substances and its preparation and use. Use of the backing of the invention is not described.

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DE 37 43 945 describes an adhesive composition for delivering substances, and the production process. In the case of the pressure-sensitive hot-melt adhesive composition described, which is based on SIS, the device is not self-adhesive. The processing ranges indicated therein lie well below those of hot-melt adhesive compositions and for such described systems would not provide sufficient anchoring of the adhesive composition. Use of the backing of the invention is not described.

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WO 96/22083 indicates a polyisobutylene adhesive for transdermal purposes, which has a tackifier with a high glass transition point. Use of the backing of the invention is not described.

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JP 07-196505 describes the administration of inkomethacin [sic] in hot-melt pressure-sensitive adhesives. In this case, a polyethylene foam is used as backing material. Use of the backing of the invention is not described.

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The object of the invention was to provide a nonwoven-based backing material which has been coated with a doped adhesive composition and is suitable for medical requirements and which, moreover, does not have the

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disadvantages known from the prior art.

This object is achieved by a nonwoven as set down in the main claim. An alternative embodiment is the subject-matter of the subsidiary Claim 2. The under-  
5 sayings [sic] embrace advantageous variants of the subject-matter of the invention.

Accordingly, a nonwoven overstitched by means of yarns  
10 is used as backing material for medical purposes, the number of stitches on the nonwoven being advantageously at least 3/cm, preferably from 5/cm to 50/cm. The ultimate tensile stress strength of the backing material is at least 10 N/cm, preferably from 20 to  
15 450 N/cm, with particular preference from 30 to 250 N/cm, and the backing material is coated partially or over its full area on at least one side with a doped adhesive composition.

20 The yarns preferably have a water absorption of less than 30%, with particular preference less than 20%. The water absorption can be regenerated by the atmospheric humidity.

25 Accordingly, materials which can be used for the yarns are, advantageously, polymeric fibres made from polypropylene, polyester, polyamide, aramid or polyethylene, and also mineral fibres such as glass fibres or carbon fibres. In addition it is also  
30 possible to use multistrand yarns or mixed multistrands, especially Sirospun yarns. For specific applications, single- or multi-strand fibre blend yarns may also be employed. Furthermore, the yarns can have been at least partly coloured in order to make the  
35 backing material more visually appealing.

For specific applications, the yarn can also be elastic. From this there is then regenerated an elastic base support having an elongation of up to 250% at a load of 10 N/cm. Mention may be made here, for example,  
5 as a polyamide yarn (Lycra<sup>®</sup>, DuPont) [sic].

A backing material of this kind generates a compression force of from 0.2 N/cm to 10 N/cm at an elongation of from 20% to 70% and is used in compression technology.

10 In the case of the alternative embodiment of the subject-matter of the invention, a nonwoven is used as backing material for medical purposes. In this case, the nonwoven is reinforced by the formation of stitches formed by loops from the fibres of the web, the number  
15 of stitches on the web being advantageously at least 3/cm, preferably from 5/cm to 50/cm. The ultimate tensile stress strength of the backing material is at least 10 N/cm, preferably from 20 to 450 N/cm, with particular preference from 50 to 250 N/cm, and the  
20 backing material is coated partially or over its full area on at least one side with a doped adhesive composition.

The backing materials are based on known nonwovens  
25 which are mechanically consolidated either by over stitching with separate yarns or by looping.

In the first case, the resulting structures are the web-yarn stitchbonds. For their production, a fibre web is taken, which can, for example, be in cross-plating  
30 configuration, and is over stitched with separate yarns in pillarstitch formation or tricot formation.

These nonwovens are known by the name "Maliwatt" (from the company Malimo) or Arachne.

With the second type of consolidation, again,  
35 preferably a cross-plated web is taken. In the course of the consolidation operation, needles draw out fibres

from the web itself and form them into loops, with stitches being formed in pillarstitch formation. This web stitchbond is in circulation under the name "Malivlies" [Mali Fleece], again from the company  
5 Malimo.

An overview of the various kinds of mechanically consolidated fibre nonwovens can be found in the article "Kaschierung von Autopolsterstoffen mit Faservliesen" [Laminating car upholstery materials with  
10 fibre webs] by G. Schmidt, Melliand Textilberichte 6/1992, pages 479 to 486.

Advantageously, the webs have longitudinal stitches, in which case the orientation of the yarns ought to be  
15 aligned in accordance with the stresses on the backing material in use.

Starting materials which can be used for the nonwoven material are generally all organic and inorganic,  
20 natural- and synthetic-based fibre materials. Examples that may be mentioned include viscose, cotton, silk, polypropylene, polyester, polyurethane, polyamide, aramid or polyethylene, and also mineral fibres such as glass fibres or carbon fibres. The present invention  
25 is, however, not restricted to the said materials; rather, it is possible to use a large number of other fibres for web formation.

The fibres used to form the web preferably have a water retention capacity of more than 0.5%, preferably  
30 between 2 to [sic] 70%, with particular preference between 3 and 50%.

In one preferred embodiment, the backing material has an ultimate tensile stress elongation of less than 40%,  
35 preferably less than 15%, with particular preference less than 10%.

For a web overstitched with yarns, this is achieved firstly by the use of a yarn material having a higher modulus of elasticity and secondly with the use of stitching which ensures a yarn position which is stretched as much as possible.

Advantageous combinations of material are, for example, yarns of high-strength polymer fibres such as polyamide, polyester, highly stretched polyethylene, or mineral fibres such as glass, and initial web materials such as cotton or staple viscose rayon.

For a web in which the formation of stitches takes place by the loops being formed from the fibres of the web, the material of the initial web should be selected accordingly; corresponding comments apply to the stitching.

It has also been found advantageous for the backing material to have a basis weight of up to  $500 \text{ g/m}^2$ , preferably from 10 to  $350 \text{ g/m}^2$ .

In one further advantageous embodiment, the backing material can be torn by hand perpendicular to the orientation of the stitches and/or in the direction of the stitches. This finds its application when the backing material of the invention is wound up on itself to form a roll.

In another embodiment, this tearability is unnecessary. In this case, the materials involved may be prepunched plaster materials.

Furthermore, the backing material may have been reinforced with one or more--monofil, multifil, staple fibre or spun fibre yarns and/or with oriented high-

strength fibres, the yarns and/or fibres having in particular a strength of at least 40 cN/tex.

In addition it is also possible to employ multi-strand yarns or mixed multistrands, especially Sirospun yarns.

- 5 For specific applications, single- or multi-strand fibre blend yarns may also be employed. These may comprise, for example, core-spun yarns or special staple fibre core-spun yarns.

- 10 An advantage here is that by combining different fibre types it is possible to achieve particular properties or specific properties in the reinforcement thread. Examples of this are the combinations of polyester or polyamide with cotton or staple viscose rayon.

- 15 The reinforcement fibres or filaments here can consist of organic or inorganic materials: for example, and preferably, glass, carbon, polyester or specific polyamides, and the reinforcement fibres may also have been at least partly coloured in order to render the  
20 backing material more visually appealing. In this way it is readily possible to differentiate visually the reinforced backing. Coloured glass or polymer filaments are particularly suitable for this purpose.

- 25 In one advantageous embodiment the backing material attains through the addition of high-strength fibres or filaments an ultimate tensile stress strength of more than 40 cN/tex, an ultimate tensile stress strength of more than 50 N/cm and an ultimate tensile stress  
30 elongation of less than 25% with a basis weight of less than 140 g/m<sup>2</sup>.

- The number of attached or introduced filaments or high-strength fibres depends primarily on the particular  
35 intended use and on the desired ultimate tensile stress strength and ultimate tensile stress elongation of the

backing material, on its inherent nature and on the respective strength of the fibres and filaments themselves, and can therefore be varied within relatively wide limits.

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Advantageous combinations of material are, for example, reinforcement filaments or fibres of high-strength polymer fibres such as polyamide, polyester, highly stretched polyethylene, or mineral fibres such as glass, and initial web materials such as cotton or staple viscose rayon.

15 In addition, the reinforcements are preferably inserted specifically in accordance with the direction of stress of the backing material, i.e. in the longitudinal direction. If more appropriate, however, they can also extend only or additionally in the transverse or oblique direction or, for example, in curved, spiral or zigzag formation, or randomly.

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In one further advantageous embodiment, the backing material can be torn by hand perpendicular to the orientation of the reinforcement and/or in the direction of the reinforcement.

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With greater strength of the nonwoven material and an increasing proportion of reinforcement fibres, the backing withstands greater stress and loading. Even very highly reinforced backing materials are able to absorb or allow the passage of large amounts of moisture, and hence provide a pleasant sensation for the user, with the reinforcements absorbing little or no moisture and so undergoing no change in their properties.

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The adhesive composition may preferably include

different active substances, the quantitative concentrations of the active substance or substances in the adhesive composition further preferably being between 0.01 to about 60% by weight, preferably from 0.1 to 20% by weight.

Under the designation "active substances" in connection with the present invention there are understood chemical elements, organic and inorganic compounds which are able to migrate from the constituents of a generic adhesive composition that comprise them and so bring about a desired effect. Among the fields of application of the adhesive composition of the invention, human and veterinary medicine is of particular importance, a configuration of the invention in plaster form being particularly preferred here.

Typical substances which may be administered in this case by way of devices produced in accordance with the invention are the following:

aceclidine, amfetaminil, amfetamine, amyl nitrite, apophedrine, atabrine, alpostadil, azulene, arecoline, anethole, amylene hydrate, acetylcholine, acridine, adenosine triphosphoric acid, L-malic acid, alimemazine, allithiamine, allyl isothiocyanate, aminoethanol, apyzine, apiole, azatadine, alprenolol, ethinazone, benzoyl peroxide, benzyl alcohol, bisabolol, bisnorephedrine, butacetoluide, benactyzine, camphor, colecalciferol, chloral hydrate, clemastine, chlorobutanol, capsaicin, cyclopentamine, clobutinol, chamazulene, dimethocaine, codeine, chloropromazine, quinine, chlorothymol, cyclophosphamide, cinchocaine, chlorambuzil, chlorphenesin, diethylethane, divinyl-ethane, dexchlorpheniramine, dinoprostone, dixyrazine, ephedrine, ethosuximide, enallylpropymal, emylcamate, erythrol tetranitrate, emetine, enflurane, eucalyptol,

etofenamate, ethylmorphine, fentanyl, fluanisone,  
guaiazulene, halothane, hyoscyamine, histamine, fen-  
carbamide, hydroxycaine, hexylresorcinol, isoaminile  
citrate, isosorbide dinitrate, ibuprofen, iodine,  
5 iodoform, isoaminile, lidocaine, lopirine, levamisole,  
methadone, methypylon, methylphenidate, mephenesin,  
methylephedrine, meclastine, methopromazine,  
mesuximide, nikethamide, norpseudoephedrine, menthol,  
methoxyfluran, methylpentinol, metixene, mesoprostol;  
10 oxytetracaine, oxyprenolol, oxyphenbutazone,  
oxyquinoline, pinene, prolintane, procyclidine,  
piperazine, pivazide, phensuximide, procaine,  
phenindamine, promethazine, pentetrazol, profenamine,  
perazine, phenol, pethidine, pilocarpine, prenylamine,  
15 phenoxybenzamine, resochin, scopolamine, salicylic acid  
ester, sparteine, trichloroethylene, timolol,  
trifluoperazine, tetracaine, trimipramine,  
tranlylcypromine, trimethadione, tybamate, thymol,  
thioridazine, valproic acid and verapamil, and also  
20 other active substances familiar to the skilled worker  
that can be absorbed through the skin, including  
mucosae. This list is of course not exhaustive.

The active substances are dispersed in the adhesive  
25 composition preferably in commercial homogenizers, such  
as for example mixers, kneading apparatus, roll mills  
or screw systems. The active substance can be added to  
the ready-prepared adhesive composition. The active  
substance can also, for example, be incorporated into  
30 an intermediate stage or into the initial mixture.

As adhesive compositions it is possible with advantage  
to use self-adhesive compositions based on natural and  
synthetic rubbers and on other synthetic polymers such  
35 as acrylates, methacrylates, polyurethanes,  
polyolefins, polyvinyl derivatives, polyesters or



silicones with corresponding additives such as tackifier resins, plasticizers, stabilizers and other auxiliaries where necessary.

- 5 The adhesive composition may additionally comprise polymers which form a physically or chemically crosslinked gel.

10 Thermoplastic hot-melt adhesive compositions, in particular, have advantageous properties and are favoured for reasons concerned with the production process.

15 Their softening point should be higher than 50°C, since the application temperature in the case of the coating is generally at least 90°C, preferably between 120°C and 150°C, or between 180°C and 220°C in the case of special adhesive compositions such as silicones.

20 If desired, postcrosslinking by means of high-energy radiation such as UV rays or electron beams may be applied.

25 Preferred hot-melted adhesive compositions based on block copolymers are notable for their diverse possibilities for variation, since the controlled reduction in the glass transition temperature of the self-adhesive composition as a result of the selection of the tackifiers, plasticizers, polymer molecule size and molecular distribution of the starting components  
30 ensures the required bonding to the skin in a manner appropriate to their function, even at critical points of the human locomotor system.

35 The high shear strength of the hot-melt adhesive composition is achieved through the high cohesiveness of the polymer. The good tack results from the range of

tackifiers and plasticizers employed.

For especially strongly adhesive systems, the hot-melt adhesive composition is preferably based on block copolymers, especially A-B-, A-B-A block copolymers or mixtures thereof. The hard phase A is principally polystyrene or its derivatives and the soft phase B contains ethylene, propylene, butylene, butadiene, isoprene or mixtures thereof, particular preference being given here to ethylene and butylene or mixtures thereof.

Polystyrene blocks, however, may also be present in the soft phase B in amounts of up to 20%. The overall proportion of styrene should, however, always be less than 35% by weight. Preferably, styrene proportions of between 5% and 30% are preferred, since a relatively low proportion of styrene makes the adhesive composition more conformable.

The controlled blending of diblock and triblock copolymers is particularly advantageous, preference being given to a proportion of diblock copolymers of less than 80% by weight.

In one advantageous embodiment the hot-melt adhesive composition has the following stated composition:

- from 10% by weight to 90% by weight of block copolymers,
- 30 - from 5% by weight to 80% by weight of tackifiers such as oils, waxes, resins and/or mixtures thereof, preferably mixtures of resins and oils, less than 60% by weight of plasticizers,
- less than 15% by weight of additives,
- 35 - less than 5% by weight of stabilizers, and
- less than 60% by weight of active substance.

The aliphatic or aromatic oils, waxes and resins used as tackifiers are preferably hydrocarbon oils, waxes and resins, the consistency of the oils, such as  
5 paraffinic hydrocarbon oils, or of the waxes, such as paraffinic hydrocarbon waxes, accounting for their favourable effect on bonding to the skin. Plasticizers used are medium-chain or long-chain fatty acids and/or their esters. These additions serve to establish the  
10 adhesion properties and the stability. If desired, further stabilizers and other auxiliaries are employed.

Filling the adhesive composition with mineral or organic fillers, fibres or hollow or solid microbeads  
15 is possible.

The self-adhesive composition has a softening point of more than 70°C, preferably from 80°C to 140°C.

20 The hot-melt self-adhesive compositions are preferably formulated so that at a frequency of 0.1 rad/s they have a dynamic-complex glass transition temperature of less than 15°C, preferably from 3°C to -30°C, with very particular preference from -3°C to -25°C.

25 Stringent requirements are placed in terms of the adhesion properties on medical backing materials. For ideal use the hot-melt adhesive composition should possess a high tack. There should be functionally  
30 appropriate bond strength to the skin and to the reverse of the backing. So that there is no slipping, the hot-melt adhesive composition is also required to have a high shear strength.

By the controlled reduction in the glass transition  
35 temperature of the adhesive composition, which is a result of the selection of the tackifiers, the

plasticizers, the polymer molecule size and the molecular distribution of the starting components, the required, functionally appropriate bonding to the skin and to the reverse of the backing is achieved.

- 5 The high shear strength of the adhesive composition which is employed here is obtained by virtue of the high cohesiveness of the block copolymer. The good tack is the result of the range of tackifiers and plasticizers employed.

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Product properties such as tack, glass transition temperature and shear stability can be quantified readily using a dynamo-mechanical frequency measurement. In this case, use is made of a rheometer

- 15 controlled by shearing stress.

The results of this measurement method give information of the physical properties of a substance by taking into account the viscoelastic component. In this instance, at a predetermined temperature, the self-  
20 adhesive composition is set in oscillation between two plane-parallel plates at variable frequencies and with low deformation (linear viscoelastic region). Via a pickup control unit, with computer assistance, the quotient ( $Q = \tan \delta$ ) between the loss modulus ( $G''$ ,  
25 viscous component) and the storage modulus ( $G'$ , elastic component) is determined.

$$Q = \tan \delta = G''/G'$$

- 30 A high frequency is chosen for the subjective sensing of the tack, and a low frequency for the shear strength.

The glass transition temperature is the temperature at  
35 which amorphous or partially crystalline polymers

undergo transition from the liquid or rubber-elastic state to the hard-elastic or glassy state, or vice versa (Römpp Chemie-Lexikon, 9th Ed., Volume 2, page 1587, Georg Thieme Verlag Stuttgart - New York, 1990).

- 5 It corresponds to the maximum of the temperature function at a predetermined frequency.

For medical applications in particular, a relatively low glass transition point is required.

Designation	T <sub>g</sub> low frequency	Conformability low frequency/ RT	Tack high frequency/ RT
Hot-melt adhesive composition A	-10 ± 2°C	tan δ = 0.35 ± 0.05	tan δ = 1.70 ± 0.10
Hot-melt adhesive composition B	-9 ± 2 °C	tan δ = 0.22 ± 0.03	tan δ = 1.00 ± 0.03

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Preference is given in accordance with the invention to self-adhesive compositions for which the ratio of the viscous component to the elastic component at a frequency of 100 rad/s and at 25°C is greater than 0.7, or to self-adhesive compositions for which the ratio of the viscous component to the elastic component at a frequency of 0.1 rad/s at 25°C is less than 0.4, preferably from 0.35 to 0.02 and, with very particular preference, between 0.3 and 0.1.

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It is also advantageous, especially with use for medical products, if the adhesive composition is applied partially to the backing material, for example by means of halftone printing, screen printing, thermoflex printing or intaglio printing, because backing materials which have been adhesively treated in a continuous applied line may, under unfavourable circumstances, on application, induce mechanical irritations of the skin and are generally impermeable to air and water vapour.

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Preference is given to application in the form of polygeometric domes and, especially, domes where the ratio of diameter to height is less than 5:1. Printed application of other forms and patterns on the backing material is also possible - for example, a printed image in the form of alphanumeric character combinations or patterns such as matrices, stripes and zigzag lines.

10 The adhesive composition can be distributed uniformly over the backing material; alternatively, it can be applied with a thickness or density which varies over the area, as is appropriate for the function of the product.

15 The principle of thermal screen printing consists in the use of a rotating, heated, seamless, drum-shaped, perforated, cylindrical screen which is fed via a nozzle with the preferred hot-melt self-adhesive composition. A specially shaped nozzle lip (circular or square bar) presses the hot-melt adhesive composition, which is fed in via a channel, through the perforation of the screen wall and onto the backing web that is conveyed past it. This web is guided by means of a counterpressure roller against the external jacket of the heated screen drum at a rate which corresponds to the peripheral speed of the rotating screen drum.

20 In this context, the formation of the small domes of adhesive takes place by the following mechanism:

The pressure of the nozzle bar conveys the hot-melt adhesive composition through the screen perforation onto the backing material. The size of the domes formed is determined by the diameter of the screen perforation. The screen is lifted from the backing in

- accordance with the rate of transportation of the backing web (rotary speed of the screen drum). As a consequence of the high adhesion of the adhesive composition and the internal cohesion of the hot-melt,
- 5 the limited supply of hot-melt adhesive composition in the perforations is drawn in sharp definition from the base of the dome that is already adhering to the backing and is conveyed by the pressure of the bar onto the backing.
- 10 After the end of this transportation, the more or less strongly curved surface of the dome forms over the pre-defined base area in dependence on the rheology of the hot-melt adhesive composition. The height-to-base ratio of the dome depends on the ratio of the perforation
- 15 diameter to the wall thickness of the screen drum and on the physical properties (flow behaviour, surface tension and contact angle on the backing material) of the self-adhesive composition.
- 20 For the screen in thermal screen printing, the web-to-hole ratio can be less than 3:1, preferably less than or equal to 1:1, and in particular equal to 1:3.

The above-described mechanism of formation of the domes

25 preferentially requires backing materials that are absorbent or at least wettable by hot-melt adhesive compositions. Non-wetting backing surfaces must be pretreated by chemical or physical techniques. This can be effected by additional measures such as corona

30 discharge, for example, or by coating with substances which improve wetting.

Using the printing technique indicated it is possible to lay down the size and shape of the domes in a

35 defined manner. The bond strength values which are relevant for use and which determine the quality of the

products formed are within very narrow tolerances in the case of proper coating. The base diameter of the domes can be chosen from 10 to 5000  $\mu\text{m}$ , the height of the domes from 20 to about 2000  $\mu\text{m}$ , preferably from 50 to 1000  $\mu\text{m}$ , the low-diameter range being intended for smooth backings and the range of greater diameter and greater dome height being intended for rough or highly porous backing materials.

The positioning of the domes on the backing is laid down in a defined manner by the geometry of the applicator unit, for example the gravure or screen geometry, which can be varied within wide limits. With the aid of the parameters indicated it is possible, by way of adjustable variables, to establish with very great precision the desired profile of properties of the coating, harmonized with various backing materials and applications.

The backing material is preferably coated at a rate of more than 2 m/min, preferably from 20 to 200 m/min, the chosen coating temperature being greater than the softening temperature.

The self-adhesive composition can be applied to the backing material at a weight per unit area of greater than 15 g/m<sup>2</sup>, preferably between 90 g/m<sup>2</sup> and 500 g/m<sup>2</sup>, with very particular preference between 130 g/m<sup>2</sup> and 500 g/m<sup>2</sup>.

The percentage of the area that is coated with the self-adhesive composition should be at least 20% and can range up to approximately 95%, for specific products preferably from 40% to 60% and from 70% to 95%. This can be achieved, if appropriate, by multiple application, in which case it is also possible, if desired, to use self-adhesive compositions having



different properties.

The combination of the preferred hot-melt adhesive composition and the preferred partial coating on the one hand ensures reliable bonding of the medical product to the skin and, on the other hand, allergic or mechanical skin irritations, at least which are visually perceptible, are ruled out, even in the case of use extending over a number of days.

10 The epilation of corresponding body regions and the transfer of composition to the skin are negligible owing to the high cohesiveness of the adhesive, since the adhesive does not attach to the skin and hair; rather, the anchorage of the adhesive composition to

15 the backing material, at up to 12 N/cm (sample width), is good for medical applications.

Because of the intended breakage points that have been formed in the coating, layers of skin are no longer displaced with one another or against one another in the course of detachment. The non-displacement of these layers of skin and the relatively low level of epilation lead to an unprecedented degree of painlessness in such strongly adhering systems. In

20 addition, the individual biomechanical control of bond strength, which exhibits a demonstrable reduction in the bond strength of these plasters, assists detachability. The applied backing material shows good proprioceptive effects.

30 Depending on the backing material and its temperature sensitivity, the hot-melt adhesive composition can be applied directly or can be applied first to an auxiliary support and then to the ultimate backing. In

35 addition, subsequent calendering of the coated product and/or pretreatment of the backing, such as corona

irradiation, may be advantageous for better anchorage of the adhesive film.

In addition, treatment of the hot-melt adhesive composition with an electron beam postcrosslinking, or  
5 a UV irradiation, may result in an improvement in the desired properties.

In a further advantageous embodiment, the self-adhesive  
10 compositions are foamed before being applied to the backing material.

In this case the self-adhesive compositions are preferably foamed using inert gases such as nitrogen,  
15 carbon dioxide, noble gases, hydrocarbons or air, or mixtures thereof. In many cases, foaming additionally by thermal decomposition of gas-evolving substances, such as azo, carbonate and hydrazide compounds, has been found to be suitable.

20 The degree of foaming, i.e. the gas content, should be at least about 5% by volume and can range up to about 85% by volume. In practice, levels of from 10% by volume to 75% by volume, preferably 50% by volume, have  
25 been found to be appropriate. Operating at relatively high temperatures of approximately 100°C and with a comparatively high internal pressure produces very open-pored adhesive foam layers which are particularly permeable to air and water vapour.

30 The advantageous properties of the foamed self-adhesive coatings, such as low consumption of adhesive, high tack and good conformity, even on uneven surfaces, owing to the elasticity and plasticity, and also the initial tack, can be utilized to best effect, very  
35 particularly, in the field of medical products.

The use of breathable coatings in conjunction with elastic and likewise breathable backing materials produces a level of wear comfort which is perceived subjectively by the user as being more pleasant.

5

A particularly suitable method of preparing the foamed self-adhesive composition operates by the foam mixing system. In this system, the thermoplastic self-adhesive composition is reactive with the intended gases such  
10 as, for example, nitrogen, air or carbon dioxide in various volume proportions (from about 10% by volume to 80% by volume) in a stator/rotor system under high pressure and at a temperature above the softening point (approximately 120°C).

15 Whereas the gas entry pressure is greater than 100 bar, the mixing pressures between gas and thermoplastic in the system are from 40 to 100 bar, preferably from 40 to 70 bar. The pressure-sensitive adhesive foam produced in this way can subsequently be passed through  
20 a line into the applicator unit. In the applicator unit, commercially customary nozzles, extruder systems or chamber systems are used.

By virtue of the foaming of the self-adhesive  
25 composition and the open pores in the composition which form as a result, and given the use of an inherently porous backing, the products coated with the adhesive composition have good permeability to water vapour and air. The amount of adhesive compositions required is  
30 considerably reduced without adverse effect on the adhesion properties. The adhesive compositions have a surprisingly good tack, since per gramme of composition there is more volume and thus more adhesion surface for wetting of the substrate that is to be bonded, and the  
35 plasticity of the adhesive compositions is increased by virtue of the foam structure. Anchoring to the backing

material is also improved by this means. Moreover, the foamed adhesive coating, as already mentioned, gives the products a soft and conforming feel.

- 5   Foaming also generally reduces the viscosity of the adhesive compositions. This lowers the melt energy, and even thermally unstable backing materials can be coated directly.
- 10   The backing material coated with the adhesive composition can have an air permeability of greater than  $1 \text{ cm}^3/(\text{cm}^2 \cdot \text{s})$ , preferably greater than  $15 \text{ cm}^3/(\text{cm}^2 \cdot \text{s})$ , with very particular preference greater than  $70 \text{ cm}^3/(\text{cm}^2 \cdot \text{s})$ , and also a water vapour
- 15   permeability of greater than  $500 \text{ g}/(\text{m}^2 \cdot 24\text{h})$ , preferably greater than  $1000 \text{ g}/(\text{m}^2 \cdot 24\text{h})$ , with very particular preference greater than  $2000 \text{ g}/(\text{m}^2 \cdot 24\text{h})$ .

- Furthermore, the backing material can also be provided
- 20   with other finishes or treatments. These include, for example, corona, flame or plasma pretreatments, in order to increase the anchoring of the self-adhesive composition to the base web. In addition, the calendaring of the backing material or of the web as
- 25   yet untreated with pressure-sensitive self-adhesive composition, for the purpose of further consolidation and/or improvement in the anchoring of the pressure-sensitive self-adhesive composition, is an advantageous treatment.

- 30
- In addition, on the side opposite to that coated with self-adhesive composition, the backing material can be finished with a water-repellent layer or impregnation which prevents rapid soaking on contact with water or
- 35   perspiration. In addition to the known impregnations, this can also be done by the sewing-on of a sheet,

advantageously a water vapour permeable sheet, by means of yarns directly during the consolidation of the web. The backing material can, furthermore, be finished with a release layer or impregnation and/or coating which  
5 reduces the bond strength of the self-adhesive composition. In this case as well, in addition to the known release materials, it is also possible to sew on a sheet, advantageously a water vapour permeable sheet, directly during the consolidation of the web.

10

Another procedure which has been found to be advantageous is the lamination of the web backing with at least one additional layer of foams or sheets, since by this means a combination of properties of particular  
15 type is obtained. A foam has a substantially higher damping quality than an un laminated backing. Sheets can be used, for example, for sealing the surface.

20

Furthermore, the backing material can be coated with metallic substances by vapour deposition.

25

Finally, following the coating operation, the backing material can be lined with a backing material which repels adhesive, such as siliconized paper, or can be provided with a wound pad or with padding.

30

It is particularly advantageous for the backing material to be sterilizable, preferably by means of  $\gamma$  (gamma) radiation. Particularly suitable for subsequent sterilization, therefore, are hot-melt adhesive compositions based on block copolymers which contain no double bonds. This applies in particular to styrene-butylene-ethylene-styrene block copolymers or styrene-butylene-styrene block copolymers. This  
35 procedure is not accompanied by any application-significant changes in the adhesive properties.

The backing material of the invention has a bond strength on the reverse side of the backing of at least 0.5 N/cm, in particular a bond strength of between 2.5 N/cm and 5 N/cm. Greater bond strengths may be achieved on other substrates.

Advantageously it has been found that a reinforced backing material with such an adhesive coating, on becoming wet through - as is unavoidable, for example, in the course of water sports activities - has a stability which is better than that of customary commercial backing material. The relative increase in the ultimate tensile stress elongation of self-adhesively treated backing materials according to the invention after becoming wet through is only half as great as in the case of customary commercial self-adhesively treated backing materials.

By virtue of this the backing materials of the invention, which indeed are thus essentially inelastic, become useful for specific medical purposes, and it is also possible to employ backing materials whose use hitherto was impossible owing to lack of strength and/or excessive elongation.

With preference it is possible to use backing materials based on wovens, knits, nonwovens or composite products, provided they otherwise meet the requirements of medical use.

#### **Example 1**

The text below describes by way of example a preferred backing material, without thereby wishing to restrict the invention unnecessarily.

The backing material used was a viscose-based nonwoven. The nonwoven was overstitched with a polyester yarn, the yarn count being 22/cm sample width. The water  
5 absorption of the polyester yarn was 0.3%. The backing material was calendered and impregnated.

The backing material thus produced had an ultimate tensile stress strength of 50 N/cm and an ultimate tensile stress elongation of 28% in the lengthwise  
10 direction. The basis weight was 120 g/cm<sup>2</sup>. Wetting the backing material completely was not possible owing to the choice of reinforcement materials. Without a load, the backing material has a thickness of 1.0 mm, which brings about a good cushioning effect.

15 The backing material had an air permeability of 100 cm<sup>3</sup>/(cm<sup>2</sup>\*s) and a water vapour permeability of greater than 2500 g/(m<sup>2</sup>\*24h) and could be torn both partly and right through by hand in both crosswise and lengthwise directions.

20

The hot-melt adhesive composition was applied to the backing by thermal screen printing.

The hot-melt adhesive composition was composed as follows:

25

- an A-B/A-B-A block copolymer, which consists of hard and soft segments, with a ratio of A-B-A to A-B of 2:1 and a styrene content in the polymer of 13 mol-%; its proportion in the adhesive  
30 composition is 40% by weight (Kraton G),
- a paraffinic hydrocarbon wax with a proportion in the adhesive composition of 51% by weight,
- hydrocarbon resins with a proportion of 7.5% by weight (Super Resin HC 140),
- 35 - an ageing inhibitor with a proportion of less than 0.5% by weight (Irganox).

- a hyperaemic active substance (nonanonyl vanillylamide); fraction of 1%.

The components employed were homogenized in a thermal mixer at 125°C. The glass transition by the abovementioned method was -9°C.

Direct coating took place at 50 m/min and at a temperature of 120°C. The backing material was partially coated with 120 g/m<sup>2</sup> using a 14 mesh screen with a thickness of 300 µm.

The bandage produced by this method exhibited reversible detachment from the skin and good permeability for air and water vapour. No skin irritations were observed, and the epilation observed following the removal of the bandage was negligible.

### Example 2

The backing material used was a viscose-based nonwoven. The nonwoven was overstitched with a polyamide yarn, the yarn count being 7/cm sample width. The backing material was calendered and impregnated.

The backing material thus produced had an ultimate tensile stress strength of 12 N/cm and an ultimate tensile stress elongation of 28% in the lengthwise direction. The basis weight was 140 g/cm<sup>2</sup>. Wetting the backing material completely was not possible owing to the choice of reinforcement materials. Without a load, the backing material has a thickness of 1.2 mm, which brings about a good cushioning effect.

The backing material had an air permeability of 80 cm<sup>3</sup>/(cm<sup>2</sup>\*s) and a water vapour permeability of greater than 2500 g/(m<sup>2</sup>\*24h) and could be torn both



partly and right through by hand in both crosswise and lengthwise directions.

This hot-melt pressure-sensitive adhesive composition  
5 was composed as follows:

- an SEPS block copolymer, which consists of hard and soft segments, with a styrene content in the polymer of 13 mol-%; its proportion in the  
10 adhesive composition is 15% by weight (Kuraray Co.)
- a paraffinic hydrocarbon wax with a proportion in the adhesive composition of 44% by weight
- an ageing inhibitor with a proportion of less than  
15 1.0% by weight (Irganox 1010 Ciba)
- salicylic acid with a proportion of 40%

The components of the adhesive that were employed were homogenized in a thermal mixer at 185°C 3.5. The active  
20 substance was added in the cooling phase at 120°C and homogenization was continued in the mixer for 130 minutes.

The softening point of this adhesive composition was approximately 85°C (DIN 52011) and the adhesive  
25 composition showed a viscosity of 2100 mPas at 150°C (DIN 53018, Brookfield DV II, Sp. 21). The glass transition by the abovementioned method was - 10°C.

Using a nozzle, the self-adhesive composition was applied over the full area to the backing. Direct  
30 coating took place at 50 m/min and at a temperature of 120°C. The backing material was coated with 170 g/m<sup>2</sup>.

The plaster material produced in this way shows a comparatively good release of the active substance.